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| EXAMINER | |
|---|---|
| WINTER, GENTLE E | |
| ART UNIT | PAPER NUMBER |
| 1746 | |

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/831,075 | BARBEAU ET AL. | |
| | Examiner | Art Unit | |
| | Gentle E. Winter | 1746 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *41-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2004 has been entered.

### *Response to Remarks*

2. Claims 41, 43-52, 62, 63, 66-68, 70, 72, and 74-76 have been amended to delete the term "about". Additionally, the limitation: "without mechanical aid" has been added and is apparently supported at page 19 line 4 *et seq*. The rejection of claim 41-80

3. The anticipation rejection of claims 41, 68, 70 and 76 in view of 5,910,420 to Tuompo et al. is maintained with respect to claims 41 and 68 and withdrawn with respect to claim 76.

4. The obviousness rejection in view of United States Patent No. 5,731,275 and Applied and Environmental Microbiology by Nishiguchi et al. is withdrawn in light of remarks and claim amendments presented in paper 032904.

5. The Remarks stated that the composition disclosed by Tuompo et al. has been "expressly excluded from the scope of the claims of the present invention (1% SDS and 0.1% or less EDTA)."

6. In reviewing the reference, Tuompo discloses:

> 0-1.0 weight-% chelating agents, preferably 0.05-0.5 weight-%.

0-2.0 weight-% detergents, preferably 0.05-1.5 weight-%.

7. See column 7, line 17-column 8, line 25.

8. The disclaimed regions are:

1-2% SDS
1.0% EDTA

1.0% SDS
0.1% or less EDTA

1-2% SDS
Mandelic acid 1%
Lactic Acid 1%
(Also excludes a mix of the above
acids with a 2% total).

9. None of the disclaimed regions encompass 0.5% EDTA and 1.5% detergent. Therefore, the reference still forms the basis for a proper anticipation rejection.

10. The Remarks further indicate:

> Tuompo et al. teach the use of a mechanical aid when they harvest a sample of microorganism; they either swab or scrub the contaminated surface. In the present invention there is no need for such mechanical aid, this is particularly emphasized in those cases where the invention is used to decontaminate small diameter water lines.

11. As an initial matter, it is noted that small diameter tubes are not claimed. Additionally, Tuompo discloses removing biofilms from "machines, equipment, tubing, air conditioning tubes". Tuompo discloses: "scrubbing the surface can make the removal of microbes more efficient prior to washing and disinfecting." Negative limitations are generally difficult to find, as it is rare that inventions are defined by what they are not. Nonetheless, in this case the

teaching that scrubbing may be used, states that it is not required. Additionally, the disclosure that tubes are treated supports the conclusion. The arguments are not persuasive.

12. The Remarks indicating that Tuompo et al. are not concerned with the "decontamination (i.e. removal of a biofilm) of a surface" is not persuasive. Applicant discloses applying a biofilm removing composition (the same composition claimed by applicants) and removing a biofilm. To suggest that the same steps with the same composition when applied to the same surfaces renders in a different result is not accepted.

13. The Remarks further assert: Tuompo et al. make use of different categories of components in their loosening compositions. Again, the claims do not reflect this. The same categories, and even the same components are contemplated by Tuompo therefore the rejection is maintained.

***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 41, 42, 44-65, 70, 71, 79, and 80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 11, 12, 14-23, 25 and 26 of U.S. Patent No. 6,762,160. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

5. As to pending claims 41, 70, and 76, the claims and the patented claims 1 and 22 disclose a method for removing a biofilm, comprising the step of contacting a surface with a composition. The composition is as follows:

| Pending claims | Reference Discloses |
|---|---|
| Effective dislodging amount of detergent (at least 0.5%) | Effective dislodging amount of detergent (at least 0.1% CPC) |
| Effective dislodging amount of detergent of salt forming acid (with disclaimers) | Effective dislodging amount of a salt forming acid (mandelic acid) |

6. Both compositions are disclosed to displace "divalent cations present in the structure of the biofilm." Similarly, claim 22 of the patent reads on the pending claim 41 in the same manner.

7. As to pending claim 42, the claim is similarly rejected in view of patented claims 2 and 23, the claims are substantively identical.

8. As to pending claim 44, the disclosed value of "at least 0.1% CPC" in patented claim 1 is deemed to read on the claimed "0.5% CPC" of pending claim 44. Patented claim 25 reads on claim 44 of the application because both the pending claims and the patented claim disclose the 0.5% CPC. It is of no consequence that patented claims disclose additional components.

9. As to pending claim 46, the disclosed value of "at least 0.1% CPC" in patented claim 1 is deemed to read on the claimed "0.5% CPC" of pending claim 46. Patented claim 25 reads on claim 46 of the application because both the pending claims and the patented claim disclose the 0.5% CPC. It is of no consequence that patented claims disclose additional components.

10. As to pending claim 47 and 71, disclosing mandelic acid at a "suitable working pH value". Patented claims 3, 4, 7, and 8 disclose mandelic acid. Since both the patent and claimed compositions are used to remove biofims, the patented claims disclose a working pH value.

11. As to pending claim 48, disclosing that both the acid and the bactericide are mandelic acid. Patented claims 3, 4, 7, and 8 disclose that the acid is mandelic acid and where the bactericide is mandelic acid.

12. As to pending claim 49, disclosing that the salt or acid is EDTA. Patented claims 5 and 6 disclose that the EDTA is the salt or acid. The 0.25% concentration is disclosed in the pending claim and in both patented claims.

13. As to pending claim 50, disclosing 0.25% EDTA, the same is disclosed in patented claims 5 and 6.

14. As to pending claim 51, disclosing 0.1% mandelic acid, the same is disclosed in patented claims 3, 4, 7, and 8.

15. As to pending claim 52, disclosing 0.1% mandelic acid, the same is disclosed in patented claims 3, 4, 7, and 8.

16. As to pending claims 53 and 54, disclosing is one or more of a laundry includes mandelic acid, the same is disclosed in claims 3, 4, 7, 8, 9, and 11.

17. As to pending claim 55, disclosing that the bactericide is hydrogen peroxide or "any bactericide having a bactericidal potency and host spectrum substantially equivalent thereto."

Patented Claim 11 discloses "any bactericide having a bactericidal potency and host spectrum substantially equivalent thereto." Therefore, the claim limitations are met.

18. As to patented claim 56, disclosing that the bactericide of claim 55 is mandelic acid, the same is disclosed in patented claim 12, and claim 11 and claims 3, 4, 7, and 8.

19. As to pending claim 57, disclosing that mandelic acid is present in the concentration 0.1%, the same is disclosed in patented claims 3, 4, 7, 8, 11 and 12.

20. As to pending claims 58-65, disclosing that the composition further includes a biofilm dislodging enhancer agent which is a calcium chelator which is EDTA in a 0.25% concentration, the claim limitation is disclosed in claims 14-21.

21. As to pending claims 79 and 80, disclosing that the composition is allowed to contact the surface for between 1 and 18 hours, this is an obvious expedient. The artisan would vary the contact time based on well-known variables including temperature and degree of biofilm build-up. The artisan would allow sufficient time for the composition to perform the indicated cleaning, and in the case of tubes used in a dentist's office would allow the solution to remain in contact with the substrate overnight.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 41-43, 45, and 64-68 are rejected under 35 U.S.C. 102(b) as being unpatentable over United States Patent No. 4,666,708 to Goldemberg et al.

As to claims 41-43, 45 and 64-67, disclosing a method for removing a biofilm from a surface without mechanical aid, comprising the step of contacting the surface with a composition comprising at least 0.1% SDS and a salt forming acid (disclosed as sodium benzoate and sodium salicylate). The claim also includes a proviso excluding certain ranges. Goldemberg discloses "sodium lauryl sulfate [SDS] is added at a concentration from 0.1% to 1.5%, plaque removal on initial use is high...". Column 4, line 33 *et seq*. The 0.1% identically reads on the claim limitation of 0.1%, it is of no consequence that additional values are also disclosed because the proviso is only applicable to compositions that include EDTA or mandelic and lactic acids, neither of which are present in the reference. As to the chaotropic agent, disclosed in connection with claims 64-68, the same is identically disclosed to be the detergent "wherein both the chaotropic agent and detergent are SDS which achieves, once reconstituted in aqueous solution, a concentration of at least 0.1%". As to the bactericide disclosed in claim 42, Goldemberg discloses ethanol at 7%. Ethanol is an effective bactericide, SDS is also known as an effective bactericide, i.e. having the ability to lyse cells.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 41, 58, 60, 64, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent No. 5,910,420 to Tuompo. See e.g. column 7, line 19 *et seq.* The method is drawn to removing biofilms (see abstract). The current claims do not address whether the biofilms are left intact or destroyed. The additional language drawn to without mechanical aid is present in the teaching. See column 4, line 13 *et seq.* Disclosing: "detaching substances in such conditions that the structure of the sample is loosened, and removal of the sample from the surface is simplified...". A dislodging amount of detergent see e.g. column 7, line 23 *et seq.* and column 8, line 8 *et seq.* disclosing a detergent. Additionally, column 7, line 11 discloses "...help to gently detach the biofilm from its surface...". It is noted that some embodiments include "scouring or scrubbing agents" see column 7, line 36 *et seq.* The reference clearly lists the concentration at 0%; furthermore, it is not clear that applicant disclaims agents added to the solution.

16. As to the effective dislodging amount of a salt forming acid, wherein the acid and its corresponding salt displace divalent cations present in the structure of biofilms. Applicant, in claim 62 discloses that EDTA is an acceptable acid. The same is disclosed at column 7, line 53 *et seq.* of Tuompo. The open claim language allows for the presence of additional components.

17. As to claims 58 and 60, disclosing that the composition includes a "biofilm dislodging enhancer agent" which is a calcium chelator. EDTA is disclosed in claim 62 to meet the claim

limitations and is disclosed at column 7, line 53 *et seq.*

18. As to claim 64, further limiting claim 58 and disclosing that the enhancer is a chaotropic agent. SDS will serve this function (see claim 66). SDS is disclosed in Tuompo. Column 7, line 53 *et seq.*

19. As to claim 68, the detergent is disclosed to optionally be SDS (sodium dodecyl sulfate) and the acid is disclosed as EDTA (ethylenediamine tetraacetic acid). The same is disclosed at column 10, line 58 *et seq.* and column 10, line 63 *et seq.* As to the negative limitation, requiring that the EDTA not be 1% and not be 0.1% or less, column 12, line 1 *et seq.* discloses *inter alia* 0.6% EDTA. Therefore, Tuompo discloses a system that is outside of the excluded range.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims and 41-43, 45, 47-71, 74, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/20737.

As to claim 41, disclosing a method of using a composition to remove a biofilm without a mechanical aid, comprising a detergent and a salt forming acid. Page 11, line 8 *et seq.* discloses "which excludes the possibility of scrubbing" is deemed to meet the "without mechanical aid" limitation. As to the composition limitations, the claims are drawn to a composition that includes a detergent and a salt forming acid. The claim excludes certain specific embodiments:

| Applicant disclaims | WO/20737 Discloses |
|---|---|
| **1-2% SDS**<br>**1.0% EDTA** | **1-2% SDS**<br>**1% EDTA** |
| **1.0% SDS**<br>**0.1% EDTA** | 1-2% **SDS** Page 7, line 6 *et seq.*<br>**1% EDTA** column 4, line 5 *et seq.* |
| **1-2% SDS**<br>**Mandelic acid 1%**<br>**Lactic Acid 1%**<br>(Also excludes a mix of the above acids with a 2% total). | **1-2% SDS**<br>**Mandelic Acid 1%**<br>**Lactic Acid 1%** |

3. The Board of Patent Appeals and Interferences have held that a prima facie case of obviousness exists when a claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 783, 227 USPQ 773, 779 (Fed. Cir. 1985) (concluding that a claim directed to an alloy containing "0.8% nickel, 0.3% molybdenum, up to 0.1% maximum iron, balance titanium" would have been prima facie obvious in view of a reference disclosing alloys containing 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium). In the instant case, applicant makes no allegation that unexpected results are achieved with the claim composition—perhaps because claim 41 does not claim a composition, but rather *disclaims* a composition—in any case, no unexpected property has been identified, other than that something other than the prior art of record range is not the only workable range. The abutting ranges are considered to be obvious variants of each other, despite that fact that at least one of the reference-disclosed regions is explicitly disclaimed. The ranges abut, and as such, there would not have been any reason that the prior art of record would not have expected the results to be achieved at ranges minutely

outside the disclosed ranges. For instance, additional EDTA might be used if the water were known to he carrying a high concentration of ions that interfered with the EDTA and its ability to function as intended.

4. As to claim 42, disclosing the presence of a bactericide, the same is disclosed at page 8 line 8 *et seq*.

5. As to claim 43, disclosing that the SDS is in a concentration of at least 0.1%, the same is disclosed with respect to claim 41, namely 1% SDS is disclosed. At least 0.1% includes 1%.

6. As to claim 45, 49, 50, 55, 58-67, and 69 disclosing a concentration of at least 0.1% SDS and a bactericide. Page 7 discloses 1% SDS and "A combination like hydrogen peroxide, SDS and EDTA is also performant." The limitations of claim 49 are also met, with the disclosure of claim 11 of the WO reference, which discloses a 2% SDS, 1% EDTA and 5% hydrogen peroxide. In both the application and the reference, the compositions perform the same function, and include the same ingredients. Therefore, the compositions are not materially different. With specific respect to claim 58-63, EDTA displaces divalent cations present in the structure of the biofilm. Specifically, addressing claims 64-67, the claims and the reference both disclose SDS in the concentration of at least 0.1%. Since the same composition is disclosed, and the method of using the composition is the same, the claim limitations are met.

7. As to claims 47, 48, 51-54, 56, 57 disclosing mandelic acid of at least 0.1%, the same is disclosed in claim 8 of the WO reference. (2% mandelic acid). In both the application and the reference, the compositions perform the same function, and include the same ingredients.

8. As to claim 70, disclosing a composition comprising 0.1% SDS and 0.1-1% salt forming acid, and 0.25-1% EDTA. The same is disclosed in the abutted ranges as discussed with respect to claim 41. The "comprising" claim language allows for the presence of additional acids.

9. As to claim 71, disclosing an effective amount of bactericide, the claim limitations are met with the disclosure of claim 11 of the WO reference, which discloses a 2% SDS, 1% EDTA and 5% hydrogen peroxide. WO references at page 7.

10. As to claim 74, disclosing that the composition additionally includes an effective amount of bactericide, disclosed as 5% H2O2, the same is disclosed in the WO references at page 7 (5% H2O2).

11. As to claims 79 and 80, disclosing that the time sufficient to dislodge the biofilm is between at least 1 hour and 18 hours. The WO reference discloses 18 to 24 hours. The 18-hour period squarely meets the limitations of the claims. See page 12 line 15 *et seq*.

12. Claims 72, 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over the WO reference and United States Patent No. 6,106,854 to Belfer et al.

13. Claim 72, discloses a method of removing a biofilm from a surface, comprising the step of contacting the surface with a composition that includes:

i. At least 0.1% SDS

ii. At least 0.1% Salt forming acid selected from a list including alternatively phosphoric and fumaric acid.

iii. At least 0.25% EDTA

14. Each and every limitation of claim 72 is identically disclosed in the WO reference, as set forth above, except the WO reference fails to explicitly disclose the specific acid that is set forth in claim 72. Belfer discloses a cleanser for the removal of biofilm from contaminated surfaces. The cleanser is disclosed to include:

> "at least one pH adjuster for acidifying the disinfectant composition from a basic or neutral condition to a slightly acidic condition having a pH in the range of 5.0 to 6.9; the pH adjuster and control agent is selected from the group consisting of ... **fumaric acid**,... **phosphoric acid**...being in the range of trace amounts to 2.0% by weight of the disinfectant composition. (emphasis added) Column 4, line 1 *et seq*.

15. In a specific embodiment, Belfer also discloses that fumaric acid as a pH adjuster (see column 11, Formulation No. 2). Belfer provides the explicit motivation for making the claimed combination; namely, Belfer states at column 4, line 8 *et seq*, that such a modification is used to control and adjust the pH. The artisan would have been motivated to use fumaric acid in an attempt to control the pH and optimize biofilm removal characteristics. It is noted that both applicant and Belfer disclose a laundry list of additives.

16. As to claim 73 and 75, disclosing that the composition additionally includes an effective amount of bactericide, disclosed as 5% H2O2, the same is disclosed in the WO references at page 7 (5% H2O2).

17. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO96/20737 in view of United States Patent No. 6,086,856 to Saferstein et al. and further in view of United States Patent No. 5,776,694 to Sheiness et al.

18. Claim 76, discloses a the step of contacting a surface with composition comprising:

At least 0.5% CPC or CPB

0.25-1% EDTA

1% salt forming acid (selected from a laundry list that includes mandelic acid and phosphoric acid), and

a buffering agent to bring the pH to about 7.5 or higher.

19. Each and every limitation of claim 76 is identically disclosed in the WO reference as set forth above, except the WO reference, fail to explicitly disclose the claimed pH (about 7.5 or higher) and the concentration of CPC. Saferstein contextually discloses the indicated pH (7.5-10) column 6, line 52 *et seq*. The higher pH is desirable in the context of oral care formulations because there is a reduced likelihood of enamel damage. Additionally, the artisan would have been motivated to increase the pH to enhance cell lysis. (See for instance United States Patent No. 5,776,694 to Sheiness et al. disclosing: "pH optima of the lysis solution will depend upon which microorganism(s) is being lysed." Sheiness goes on to disclose: "substantial lysis was observed across the entire pH range from about 6.0 to about 11.5.")

20. As to the use of CPC, the art recognizes that the cationic oral quaternary ammonium halide antimicrobials, such as cetylpyridinium chloride exhibit surfactant properties. See Saferstein column 7, line 47 *et seq*.

21. Saferstein goes on to state: "for the purpose of providing surfactancy as well as their other functions, such cationics are preferably used herein at the high end of their normal 0.005% to 1% by weight use range." It is noteworthy that claim 76 is not drawn to the removal of a biofilm but is drawn to a one step method, comprising contacting a surface with a solution. The WO reference discloses that the chelating action of EDTA is useful in breaking down the biofilm. The artisan would have been motivated to make the combination for the reasons set forth on page 10, line 9 *et seq* of the WO reference. Namely, "a cationic detergent and cetylpyridinium chloride (CPC) has not been tried but *it is believed that such a composition would be more suitable that the composition SDS/CPC*". [Emphasis added]. Applicant admits this in applicant's admitted prior art in applicant's specification at page 3 line 28 *et seq*.

22. Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldemberg.

23. Claim 77 is drawn to a method for removing a biofilm from a surface without mechanical aid, comprising the step of contacting the surface with a composition comprising a final concentration of SDS 0.25, sodium benzoate 2%, and sodium salicylate 0.2%. Goldemberg discloses "sodium lauryl sulfate [SDS] is added at a concentration from 0.1% to 1.5%, plaque removal on initial use is high...". Column 4, line 33 *et seq*. The artisan would have been motivated to select a SDS concentration that is at once effective and as low as possible in an effort to provide an effective cleaner at minimal cost. The exact value would be selected based on factors including the amount of material that the surfactant is to act on and the nature of other comparable components that are present.

24. With respect to the sodium benzoate, the reference discloses: It has also been found that when sodium benzoate is employed in combination with the other ingredients of the dental rinse of this invention, the plaque loosening and retarding properties of the composition are significantly enhanced." And continues "The sodium benzoate is preferably employed at a level of a least about 1% by weight, and most preferably at least about 2% by weight of the composition." This reads identically on the claimed concentration. Column 5, line 32 *et seq.*

25. As to the sodium salicylate, the reference discloses: "The sodium salicylate or other analgesics preferably comprise about 0.1 to 1%, and most preferably, about 0.2 to about 0.5% by weight of the rinse." Again, the value reads identically on the claimed concentration.

26. As to claim 42, disclosing an effective amount of a bactericide, Example 4 at column 9, line 34 *et seq.* discloses ethanol at about 7%, which has bactericidal properties.

27. Claims 41 and 78 rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 0109279 in view of United States Patent No. 5,731,275 to Prevost et al.

28. Claims 41 and 78 disclose a method for removing a biofilm from a surface without mechanical aid, comprising the step of contacting the surface with a composition comprising the step of applying a composition to the surface. The composition of claim 78 is disclosed, verbatim in claim 4 of EPA 0109279. The applicant varies from the present invention in that it is used to sterilize surfaces as opposed to remove biofilms. Prevost discloses that a combination of a detergent, denaturing agent and bactericide makes an effective decontaminating solution for biofilms. The artisan would have been motivated select a composition that would sterilize

without damaging equipment, and remove biofilm. Since Prevost and EPA 0109279 both disclose a detergent, denaturing agent and bactericide, the artisan would have been motivated to use the EPA 0109279 composition because, in addition to having the characteristics of a biofilm remover, the EPA 0109279 reference discloses that the composition will not corrode metal. See page 2 line 25 *et seq*.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gentle E. Winter whose telephone number is (571) 272-1310. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Questions on access to the Private PAIR system should be directed to the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gentle E. Winter
Examiner
Art Unit 1746

July 2, 2004